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(54) Title: ENCAPSULATION OF CAFFEINE (57) Abstract Encapsulations containing caffeine with organoleptic properties such as bitter taste, have a mixture of caffeine with oleaginous material.		

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ENCAPSULATION OF CAFFEINE

Field of the Invention

The present invention relates to the art of unique delivery systems for comestibles, especially to novel methods of making a functionalized confectionery mass which do not require cooking to dehydrate, as well as products therefrom. More particularly, the invention relates to comestible delivery systems, uncooked confectioneries and nougats, and methods for making same. The invention also provides a soft, chewy confectionery nougat-type composition in the form of a bite-size serving containing an active ingredient, advantageously a bitter-tasting or organoleptically unpalatable active.

Also provided as part of the invention are edible, taste-masked confectionery formulations containing one or more active ingredients which are encapsulated to taste-mask their poor organoleptic qualities.

Further provided is a novel encapsulation containing an active ingredient such as caffeine, which may be utilized as part of a comestible delivery system.

Background of the Invention

It is generally considered a necessity in the art of preparing food or drug delivery systems like confectionery masses such as chewy nougats to use water as a mixing medium and source of hydration for ingredients. Specifically with respect to nougats, a typical recipe calls for soaking egg albumen in water over a period of time, such as overnight, in order to fully hydrate the proteinaceous material contained therein. Following hydration the egg albumen is stirred and strained before being beaten into a stiff foam. Other ingredients such as sugar, honey, and corn syrup are separately cooked with water to a relatively high cooking temperature of from about 135°C to about 138°C to achieve the necessary interaction among the ingredients. The cooked mixture is then poured into the egg and beaten with a nougat mixer. This conventional nougat preparation method requires cooking the ingredients and using a significant

amount of water to serve as a mixing medium and source of hydration.

The amount of water used is much larger than that which would permit the formation of the solid nougat. The water is supplied in more than sufficient quantity to ensure that specific ingredients are wetted and functionalized. Consequently, the excessive moisture must be driven off as much as possible to achieve the structural integrity and consistency necessary for the end product. Unless the water is forcibly removed, the process will result in an incoherent product having no significant structural integrity.

Removal of excess water is generally undertaken by a combination of mixing and boiling to drive off the moisture and bring the mass to proper viscosity and consistency. This process, however, can be highly energy-inefficient and very costly as it requires heat, excessive handling of nougat masses, flashing off of some critical fluids, and an inability to incorporate heat sensitive materials, as well as a less desirable overall stability of the product. Moreover, it is not effective in completely eliminating a substantial amount of the moisture contained in the confectionery mass.

One of the unwanted results of inefficient dehydration is that water remains as a separate phase in the end product. This water is not bound to other ingredients and can be referred to as free moisture or unbound water. Free moisture can detract from the end product because it weakens the structural integrity and/or reduces the quality of organoleptic perception. Moreover, excessive free moisture results in higher water activity, and thereby provides an environment in which microorganisms can grow. Microbiological growth in food products has also been used to measure the existence of free moisture.

Many food preservation processes attempt to eliminate microbial growth and spoilage by lowering the availability of water to microorganisms. Reducing the amount of free moisture or unbound water also minimizes other undesirable chemical changes which can occur in foods during storage. The processes used to reduce the amount of unbound water in foods include techniques such as concentration, dehydration, and freeze-drying. These processes require intensive expenditure of energy and are not cost efficient.

The present invention overcomes the difficulties set forth above as well as other difficulties generally associated with the prior art. In particular, both the necessity of

cooking the confection and using excessive water to mix and hydrate one or more ingredients is eliminated, and the method and product of the invention are obtained without any need for dehydration. Consequently, the detrimental heat history generally associated with energy-intensive procedures is also eliminated. Separation of the water from the resulting product is avoided and the lowered water activity results in a product having superior physical, storage, and organoleptic properties with reduced microbial growth problems.

Finally, the present invention addresses the issue of producing a chewy nougat confectionery formulation containing an active substance which is highly palatable and is storage stable. The composition of the invention also effectively solves the problem of taste-masking the bitter-tasting and/or disagreeable odor characteristics of many active substances without diluting their potency or efficacy.

In particular, caffeine is desirable as a drug or nutritional supplement to enhance alertness. As many caffeine "addicts" will attest, the compound is mandatory for remaining awake and focused throughout the day. Unfortunately, raw caffeine has extremely undesirable organoleptic qualities. It is gritty with a bitter, foul taste.

Caffeine is currently available in a variety of liquid beverages, most notably tea and coffee. Other formulations containing caffeine presently exist in pill or powder form to be swallowed with a glass of water. What is needed in the art is a palatable formulation of caffeine which can be blended into a wide variety of confectionery systems for oral administration. The caffeine should be taste-masked, so its bitterness cannot be sensed by the consumer. Also needed is a pleasant-tasting confectionery or chewing gum product which contains a suitable taste-masked dose of caffeine.

Summary of the Invention

The present invention is a method of making a unique food and drug delivery system, and especially a novel confectionery delivery system, especially a nougat, via hydration, without the need for cooking or subsequent dehydrating in order to produce the confectionery mass. The present invention also includes the product resulting from the new method of preparation.

In one embodiment, a saccharide-based component is combined with a hydrated

hydrobinding component to form the confectionery of the system.

In a more preferred embodiment, it is also contemplated that one or more active ingredients can be included in the confectionery mass which is formed as a result of the present invention. The active ingredients are typically ones which are intended to produce a biological and/or chemical response in the body. One or more of these active ingredients may be encapsulated using a novel combination of materials, hereinafter described. The active ingredient encapsulation may then be included as part of the confectionery mass.

Especially preferred actives as part of the composition of the invention include bioassimilable sources of many pharmaceuticals, medicinal substances, vitamins, minerals and nutraceuticals. Those substances with an offensive taste or smell are particularly desirable. Other preferred actives include many types of chemical substances which cannot normally be delivered via a confectionery delivery system because of the attendant organoleptic problems associated with these substances. Such actives can include the bitter drug caffeine, for example.

The product resulting from the present invention is unique because it requires no cooking and no dehydration by traditional heating at high temperatures to produce, and has substantially no phase separation of moisture. The only moisture present is bound therein in an amount sufficient to functionalize the mass. Thus, the product can be prepared without cooking.

As herein further described, the product may also be prepared using flash-flow processing, low or high shear mixing, or any combination thereof. As a result of one or more of these methods, many of the attendant processing problems associated with bioaffecting additives can be substantially reduced or eliminated.

The final product furthermore exhibits improved content uniformity and improved organoleptic qualities. Overall, the formulated confectionery delivery system herein described is more tasty (no grit or chalkiness) and is highly storage stable as compared to many of the current formulations available in the art.

In a further embodiment of the invention, there is provided a method of encapsulating active substances, especially bitter-tasting actives, so as to effectively mask their unpalatableness. The encapsulated compositions so produced containing one

or more of these organoleptically unpleasant actives are suitable for inclusion in a confectionery delivery system, especially the chewy nougat delivery system described above.

In still another embodiment of the invention, there is provided an encapsulated caffeine formulation which effectively masks the taste and other undesirable organoleptic attributes of caffeine.

The invention also provides a method of masking the taste and poor mouthfeel of caffeine which comprises combining a suitable quantity of caffeine into an encapsulated matrix.

Further provided is a palatable comestible confectionery or chewing gum composition containing an effective amount of encapsulated caffeine.

Detailed Description of the Invention

The confectionery-mass delivery systems in accordance with the present invention includes a saccharide-based component and a hydrobinding component, the latter component being hydrated sufficiently to provide controlled water delivery to the saccharide-based component and/or other ingredients. Controlled water delivery means delivery of water in an amount and at a rate which is sufficient to provide internal viscosity and cohesivity to the saccharide-based component. The word hydrated as used in the term hydrated hydrobound component herein means containing sufficient water to provide the requisite controlled water delivery.

Furthermore, the system created by the combination of the present invention is a water-starved system, which means that the system has only enough moisture to bind the ingredients together and provide internal lubricity. Since the ingredients are competing for moisture due to enhanced wettability, there is virtually no free moisture available to separate from the mass, and thus no attendant problems associated therewith.

In the present invention, the hydrobinding component is used to provide a functionalized hydrobound confectionery mass. The hydrobinding component is thus an ingredient which imbibes, delivers and maintains water in an amount sufficient to functionalize the resulting mass. The water which is hydrobound does not separate and

become a separate phase. A hydrobinding component cooperates with other ingredients to deliver and maintain water sufficient to functionalize the mass of ingredients (including those ingredients which may have been subjected to flash-flow processing - e.g. the saccharide-based component, hereinafter described).

Ingredients useful in the present invention which make up the hydrobinding component include, for example, proteinaceous materials known to those skilled in the art, and preferably gelatins of various grades and types. Also preferred are food grade gums such as gum arabic, carrageenan, guar gum, and locust bean gum, and mixtures thereof. Hydrobinding components constituting a mixture of ingredients are desirable in some situations. Highly preferred hydrobinding ingredients include, for example, a mixture of gelatin and gum arabic, or a mixture of carrageenan and locust bean gum with a crosslinking agent, such as potassium citrate or potassium chloride, which induces crosslinking between these materials. These mixed hydrobinding materials are advantageous not only for their hydrobinding capacities, but also because they impart viscoelasticity to the resulting confectionery. It is possible that crosslinking in these materials contributes to their desirable physical properties. The hydrobinding material can also benefit from inclusion of a wetting agent or humectant such as a polyol known in the art, desirably glycerin, or other functionally similar materials which are commercially available.

The hydrobinding component will comprise about 0.5-20% of the confectionery system of the invention. Preferably, the hydrobinding component will be within the range of about 5-15%, and even more desirably within the range of about 5-12% of the final confectionery composition. Of the foregoing hydrobinding component, water will comprise about 10 - 80% thereof, and preferably about 10 - 60% of the hydrobinding component. The proteinaceous material or the gum, or combination thereof, will make up about 0.5 to 60% of the hydrobinding component, and more preferably be within the range of about 3 to 50%, more desirably about 3 to 20% (unless otherwise set forth, all %s herein are percentages by weight, or weight percent).

Another material which may be included as part of the hydrobinding component is a wetting or softening agent, such as a polyol, preferably glycerin, which may be included in amounts equal to about 0 - 75%, preferably about 0.1 - 70% of the

composition of the invention, even more desirably about 10-70%. The glycerin (or other selected material) can also function as a humectant, and thereby keep moisture in the system.

The hydrobinding component may also be aerated, preferably in the presence of an aerating agent, before or after being combined with the other components making up the confectionery composition of the invention. Preferred aerating agents include egg whites and soy protein. Aerating agents are desirably added in amounts within the range of about 0 - 5%, more desirably 0.1 - 3% of the confectionery mass of the invention.

It is also within the scope of the invention that ingredients which are used in the hydrobinding component may also be added as part of the saccharide-based component, hereinbelow described. Thus, in a somewhat less preferred embodiment, gelatins and food grade gums such as gum arabic, carrageenan, guar gum, locust bean gum, etc., can be used to prepare the saccharide-based component, e.g., by being included in the feedstock used to prepare that component.

The invention also employs a saccharide-based material as another major component (the hydrobinding material being the heretofore set forth first major component). The saccharide-based material can include any of a large variety of saccharide materials, such as small sugars, e.g., dextrose, sucrose, fructose, etc., and larger saccharides, e.g. oligosaccharides and polysaccharides such as corn syrup solids and polydextrose, as well as mixtures of two or more of these materials.

Corn syrup solids are highly preferred for use as the saccharide-based material in the composition of the invention. Corn syrup solids are commonly known as maltodextrins. Maltodextrins are composed of water soluble glucose polymers obtained from the reaction of the starch with acid or enzymes in the presence of water.

Polydextrose is a non-sucrose, essentially non-nutritive, carbohydrate substitute. It can be prepared from polymerization of glucose in the presence of polycarboxylic acid catalysts and polyols. Generally, polydextrose is known to be commercially available in three forms: Polydextrose A and Polydextrose K, which are powdered solids, and Polydextrose N supplied as a 70% solution. Each of these products can also contain some low molecular weight components, such as glucose, sorbitol, and

oligomers.

Sugars can also be used as saccharide-based materials according to the invention. Sugars are those substances which are based on simple crystalline mono- and di-saccharide structures, *i.e.*, based on C₅ (pentose) and C₆ (hexose) sugar structures. Sugars include dextrose, sucrose, fructose, lactose, maltose, etc., and sugar alcohols such as sorbitol, mannitol, maltitol, etc. Of these, fructose and/or maltose may often be especially desirable.

Typically, the foregoing saccharide-based component can comprise about 30 - 99.5% of the confectionery delivery system according to the embodiments herein set forth. Preferably, there will be about 40 - 75% of this component present, and even more desirably about 50-70% present. In addition, those skilled in the art may discover a higher or lower percentage of the saccharide-based component, or other ingredients herein set forth, will produce a suitable final product, depending upon the final characteristics, *e.g.* texture, mouth feel, juiciness, product consistency, etc., which are desired. A highly preferred saccharide-based material will comprise a mixture of corn syrup solids and fructose in a ratio range of approximately 50/50 or 30/70.

In addition to the heretofore described hydrobinding- and saccharide-based components, other materials may also be incorporated into the confectionery composition of the invention, to enhance its appearance, taste, texture, and other organoleptic properties, or to effectively taste-mask many unpleasant actives, hereinafter described. Such enhancing materials can include, for example, flavors, sweeteners, colorants, surfactants or emulsifiers, and fats or oils. Any one or a combination of more than one of the foregoing may comprise from about 0 - 20% of the confectionery mass, and more desirably be within the range of about 5 - 10% or even up to 15% of the comestible mass.

Flavors may be chosen from natural and synthetic flavoring liquids. An illustrative list of such agents includes volatile oils, synthetic flavor oils, flavoring aromatics, oils, liquids, oleoresins or extracts derived from plants, leaves, flowers, fruits, stems and combination thereof available to the skilled artisan.

Other flavorings may include whole and partial fruits and nuts, peanut butter, candy bits, chocolate chips, bran flakes, etc.

Sweeteners may be added to the confectionery system of the invention. These may be chosen from the following non-limiting list: glucose (corn syrup), dextrose, invert sugar, fructose, and mixtures thereof (in addition to those which may be utilized as part of the saccharide-based component), saccharin and its various salts such as the sodium salt; dipeptide sweeteners such as aspartame; dihydrochalcone compounds, glycyrrhizin; Stevia Rebaudiana (Stevioside); chloro derivatives of sucrose such as sucralose; sugar alcohols such as sorbitol, mannitol, xylitol, and the like. Also contemplated are hydrogenated starch hydrolysates and the synthetic sweetener 3,6-dihydro- 6-methyl-1-1-1,2,3-oxathiazin- 4-one-2,2-dioxide, particularly the potassium salt (acesulfame-K), and sodium and calcium salts thereof. Other sweeteners may also be used. The sweeteners are added in amounts equal to about 0 - 10% of the composition, and preferably about 0.1 - 5%.

Surfactants or emulsifiers may also be included in the composition of the invention. These may be any food grade emulsifying material, for example, lecithin or other phospholipid material, monoglycerides and/or diglycerides, and mixtures thereof in amounts of from about 0 - 3%, more desirably about 0.1 - 1%.

Fats may also be included in the composition, and these can include partially or entirely unsaturated fats such as palm oil and cocoa butter. Hard fats having melting points above body temperature (37 degrees C), and soft fats having a melting point of about or below body temperature, can be used alone or in combination. The texture and mouth feel of the resulting confection can be influenced by selecting the types and amounts of fats included in the saccharide-based component. Fats marketed under such trade names as Durem and Paramount have been found to be useful. Those skilled in the art will find that fats are optional as part of the composition of the invention, and may be eliminated altogether if so desired. Thus, fats will comprise about 0 - 10% of the product herein set forth, preferably less than about 7%, and even more preferably less than about 5%.

Additional materials which can be incorporated into the confectionery composition include, for example, biologically and chemically active ingredients such as medicinal substances, e.g. drugs, pharmaceuticals and antacids. These are referred to herein as active ingredients. Active ingredients may make up from about 0 - 50% of

the product of the invention, and even more depending upon the needs and abilities of those skilled in the art. It is preferred, however, to include up to about 40% of active substance in the compositions set forth herein.

As active ingredients, the aforecited U.S. Patent No. 5,587,198 contains a non-exhaustive listing of active substances, the salient portion of which is incorporated herein by reference. More specifically, actives would include many OTC preparations suitable for oral consumption, as for example, analgesics such as acetaminophen, ibuprofen, antihistamines and cough and cold relief actives. Other examples of such actives would include vitamins and minerals (e.g. calcium, magnesium, etc.), as well as protein from animal and/or vegetable sources (to be distinguished from the proteinaceous material utilized in the hydrobinding component), and soluble and/or insoluble dietary fiber. Also to be included as actives include such naturally-derived products as botanical substance extracts such as derivatives of plants and herbs, as for example, bark, stem, leaves, roots, berries and flowers. The botanical extracts would much desirably be those which are recognized for their nutraceutical properties. Non-limiting examples of these botanical extracts could include ginseng, ginkoba, ginkgo biloba, St. John's wort, and the like. One source for these materials may be found under the brand name STAND-EX from Bio-Botanica, Inc., including Lipo Chemicals. Other nutraceutical ingredients are also contemplated by the invention.

Other bulky materials can also be included as actives, i.e. active ingredients, in the confectionery composition of the invention. These can include such food material as fiber and other vegetable and fruit materials. Of course, useful comestible delivery systems can also be produced wherein as little as only a trace amount of the total weight of the product is a deliverable active ingredient.

In one especially desirable embodiment of the invention, the chewy confectionery composition herein set forth contains one or more active substances which until now could not be easily administered via a chewable delivery system because of their relatively poor organoleptic properties. These biological and chemical substances are fairly unpleasant looking, tasting or smelling, have a disagreeable mouthfeel, are difficult to swallow, or are otherwise difficult to administer. Chewing these substances would normally only exacerbate the unpleasantness. The unique confectionery system

herein provided effectively taste masks many or all of these substances, and thereby functions as a unique delivery system for these actives. Thus, it is clearly within the scope of the invention to provide a confectionery system containing all manner of unpleasant actives which can be easily masticated and swallowed like any nougat-type candy. These compositions are sweet-tasting and therefore are easily administered. At the same time, the heretofore described components constituting these formulations effectively taste-mask the bitterness and bad taste associated with these myriad drugs, food substances and nutraceuticals.

One such active as part of the invention is caffeine. The drug itself has long been recognized as enhancing alertness. It can be provided as a nutritional supplement for those who wish to remain awake and cognizant for extended periods. Unfortunately, caffeine is an extremely bitter tasting white powder, and therefore would not normally be considered a likely candidate for inclusion in a typical chewy confectionery formulation. As part of the composition of the invention, however, it is rendered into an extremely delicious, chewable form with excellent mouthfeel. The chewy confectionery herein described thus functions as a delivery system for the caffeine, as well as for other active substances. When included, a dosage of caffeine within the range of about 0.1 to 500 mg is recommended. Preferably, a single serving should contain about 10 to 150 mg of caffeine. It is especially desirable to include about 25 to 100 mg. in a single dose. On a weight basis, any caffeine will typically make up about 0.1 to 5% of the final nougat confectionery composition of the invention, and more desirably be within the range of about 0.5 to 2%. These amounts can vary, depending upon the caffeine loading desired by the skilled artisan.

Other active ingredients to be included with the caffeine can include various nutraceutical-type products, as heretofore described in the amounts set forth. For example, an active ingredient formulation could include caffeine together with ginseng or green tea extract.

Caffeine and any other active ingredients, suitable for inclusion in the chewy confectionery heretofore described, may be provided in the form of an encapsulation. An encapsulated caffeine matrix can provide for more content uniformity in the final confectionery formulation. Encapsulation may also impart a greater degree of stability to

the active during relatively prolonged periods of commercial storage. Encapsulating caffeine can further enhance the hydrophilicity of the less water-soluble versions of the compound, and can also act to regulate the dissolution of the more highly soluble forms of the drug.

An encapsulated caffeine matrix is herein provided. The encapsulated matrix comprises caffeine as a primary component. Suitable caffeine may be obtained from a variety of suppliers in the food, nutraceutical and pharmaceutical industries. Preferred is anhydrous caffeine. In most embodiments herein provided, the caffeine will comprise about 0.1 to 80% of the encapsulated matrix, and more preferably will be within the range of about 10 to 50% thereof. Especially desirable will be a caffeine loading within the range of about 20 to 40%. The loading of caffeine will depend upon the particular dosing requirements desired by the skilled artisan, and therefore can vary somewhat from the ranges set forth above.

Encapsulation of caffeine may be accomplished by methods known in the art. In order to effectively encapsulate the active compound, one or more food-grade materials are employed as processing aids. These edible materials typically comprise one or more oleaginous substances (fats and oils), and may also include saccharides, proteins and other non-toxic polymeric material (such as microcrystalline and cellulosic material), especially those with emulsifying properties. Highly suitable encapsulation processing aids are preferably oleaginous materials, and therefore any one or more oleaginous food and pharmaceutical grade materials may be utilized for this purpose. It is believed that the oleaginous and other encapsulating material surrounds and enrobes individual particles of the active caffeine compound, thereby creating a matrix of several thousand or more tiny individually enrobed particles once combined into a final comestible confectionery or chewing gum composition.

Especially suitable oleaginous encapsulating material for use with caffeine includes various food-grade oils and fats available in the industry. Of these, those with emulsifying properties are particularly preferred. Vegetable and animal oils and fats may be utilized for this purpose. Stearine (a partially hydrogenated soybean oil), for example, is highly desirable as an encapsulating agent. Other useful oils include canola and cottonseed. Also useful are one or more medium chain triglyceride (MCT) oils.

Glycerols, mono-, di- and triglycerides and their corresponding fatty acid oils are especially preferred. The glycerol and glyceride families have now been discovered to be especially useful in enrobing substances with undesirable taste and texture properties, and in particular caffeine. A combination of one or more of any of the foregoing oils and fats may also be useful. The encapsulating material(s) will typically comprise about 0.5 to 99% of the caffeine encapsulation matrix, and more desirably, will be within the range of from about 10 to 80% thereof. Even more desirably, this material will comprise about 20 to 70% of the encapsulated caffeine matrix.

An especially desirable combination of encapsulating materials will comprise stearine, carnauba wax and one or more glycerides or glycerol derivatives. Of the latter, the mono- and di-glycerides are particularly preferred. In at least one embodiment of the invention, the aforesaid combination may be utilized to encapsulate caffeine without the use of additional flavors and/or sweeteners in the encapsulated matrix. It is particularly desirable to utilize this formulation in confectionery bases which typically have substantially non-acidic flavors, for example, chocolate and caramel-based comestible confectioneries. The loading of glycerides, and in particular a combination of mono- and diglycerides, should be at least about 3% of the formulation, and in certain embodiments should preferably be at least about 5% of the encapsulated matrix. A preferred range of glycerides is about 3 - 15%, with about 3 - 8% being particularly preferred because it has now been found that in these embodiments the caffeine is successfully taste-masked, *i.e.* there is substantially no perception of either the taste or the texture associated with the compound, without the need for extra substituents such as sweetening agents or flavors.

In another embodiment of the invention, a taste-masked caffeine encapsulation is prepared which utilizes at least one component selected from the group consisting of flavorants and sweeteners. Flavorants can include natural and synthetically derived flavors, oils, and essences typically utilized in the confectionery industry. For example, cocoa bean extract, cocoa powder and even chocolate may be utilized. In addition, fruit essences and flavors are also contemplated. These would include citrus-derived flavors such as lemon, lime, orange and grapefruit, etc., as well other flavors such as cherry, apple, pear, grape, strawberry, raspberry, tutti frutti and the like. Mint flavorings such as peppermint, spearmint, wintergreen and menthol are also contemplated. The quantity of

flavorants or flavoring agents is typically within the range of about 0.1 - 25%, more preferably 0.1 - 10% and more desirably should comprise about 0.5 to 15% of the encapsulated caffeine matrix.

In certain embodiments, cocoa powder as one flavorant is especially desirable for use with confectionery bases containing cocoa-compatible flavors, such as chocolate and caramel.

Sweeteners as part of the encapsulation are typically chosen from the listing of saccharide materials available in the food industry. These materials will include mono-, di-, tri- and polysaccharide material, either alone or in combination, and their related oligomers. By way of illustration, invert sugar, sucrose, fructose, maltose, dextrose, polydextrose, polydextrin, glucose (corn syrup), maltodextrin (corn syrup solids) etc. are just some examples of suitable carrier material. Other highly suitable sweeteners include saccharin, aspartame, acesulfame, sucralose, and sugar alcohols such as sorbitol, mannitol, maltitol, isomalt, xylitol as well as other commercially available sweeteners such as the dihydrochalcone compounds, glycyrrhizin, glycerine, Stevia Rebaudiana (Stevioside), and the hydrogenated starch hydrolysates. Of these, aspartame is preferred. The skilled artisan may find that other suitable flavorants and/or sweeteners may be utilized as well. Sweeteners will comprise about 0.1 to 25% of the final caffeine encapsulated matrix. Even more desirably, one or more of these sweeteners will make up about 0.5 to 10% of the matrix.

The encapsulated matrices comprising a sweetener and/or flavorant will also utilize one or more of the oleaginous encapsulating aids heretofore described, together with the caffeine as set forth above. In those embodiments wherein a particularly strong masking flavor is utilized from a substantially non-fruit source, such as cocoa, cocoa powder, chocolate or coffee for example, then the amount of glycerides present in the final encapsulated matrix will preferably be within the range of about 0.5 to less than about 3%, with about 1 to 2% being desirable. It has now been found that in certain embodiments, such as a cocoa-flavored caffeine encapsulation, less glyceride material may be utilized when sweeteners and/or flavorants also comprise the encapsulated matrix.

In yet another encapsulation formulation herein provided, additional ingredients such as one or more binding agents to further bind and stabilize the actives and/or

flavorants and sweeteners are utilized. Binding agents will typically include the food-grade gums. These can include, for example, gum arabic, carrageenan, guar gum, and locust bean gum, and mixtures thereof. Other food-grade gums are also contemplated. In addition, gelatin may also be utilized, but this is somewhat less preferred.

Binding agents are preferred for use in those encapsulated caffeine matrices wherein a somewhat less organoleptically powerful flavorant or is used or for a flavorant having an acidic moiety, such as those derived from fruit essences, and in particular, citrus oils and flavors. In these embodiments, the oleaginous encapsulating material as heretofore specified is utilized. In addition, the quantity of one or more glycerides utilized is at least about 3% of the formulation, more preferably at least about 5% of the encapsulated matrix. A preferred range of glycerides is about 3 - 15%, with about 3 - 8% being particularly preferred. It is also useful in certain fruit-flavored formulations, e.g. citrus-flavored formulations, to utilize both a source of flavorant, e.g. sour or acidic citrus-type flavorant, together with at least one sweetener. In these embodiments, the sweetener should comprise at least about 1% of the caffeine encapsulation formulation, and more preferably at least about 2% thereof.

Other ingredients may be optionally included in the caffeine encapsulation matrix according to one or more of the embodiments herein described, if desired by the skilled artisan. These may include other chemical or biological stimulants known in the art. Particularly preferred may be those substances which complement the action of the caffeine. Botanical substances such as ginseng and green tea extract may be chosen by the skilled artisan. Optional ingredients are included in the encapsulated caffeine matrix in amounts of from about 0 to 25%, more preferably about 0 to 15% by weight.

Low and high shear mixing apparatus are especially useful for preparing caffeine encapsulations through the utilization of a Littleford or Hobart mixer, or both. Spray-drying and extrusion methods are also available to encapsulate caffeine. Other highly suitable methods include flash-flow processing as described in U.S. Patent No.s 5,236,734, 5,238,696, 5,518,730, 5,387,431, 5,429,836, 5,549,917, 5,556,652, 5,582,855 and most recently, 5,834,033. In particular, U.S. Patent No. 5,380,473, sets forth a process in which the temperature of a nonsolubilized feedstock carrier is increased to a point where it will undergo internal flow, followed by ejecting a stream of the feedstock

and then subjecting it to disruptive fluid shear force which separates it into separate parts or masses which have a transformed morphology. Also disclosed in the '473 reference is an apparatus with a high pressure nozzle for changing the morphology of the feedstock. Variations of the apparatus and method set forth in the '473 reference are also possible. For example, the nozzle utilized to impart shear force to the feedstock material may be inverted upwards so as to emit the encapsulation in an upwards manner.

After encapsulation, the formulated ingredients are collected as an encapsulated caffeine matrix in particulate form, which is preferably substantially dry to the touch. The final composition is thus suitable for further blending or admixture with a wide variety of confectionery bases, including for example, candy, nougats and chewing gums according to methods known in the art.

In an especially preferred embodiment, the various caffeine encapsulations may be admixed with one or more embodiments of the chewy nougat confectionery compositions heretofore described. These chewy confectionery products according to the various embodiments of the invention are tasty and sweet, with a smooth nougat-like texture and consistency, with no grit or chalkiness. These products are well hydrated, and yet evidence no phase separation of moisture upon extended periods of storage. They require no dehydration to produce, i.e., the product can be prepared without cooking. The only moisture present is supplied by the hydrated hydrobinding component in an amount sufficient to functionalize the mass. No excess water is thus present, and thus the final product of the invention is stabilized with regard to nutritional content, microbial growth, organoleptic characteristics and other factors.

In the present invention water activity is significantly lower than water activity of similar products found in the candy bar industry. For example, candy bars usually have a water activity of 62% - 68% equilibrium relative humidity (ERH). The confectionery product of the invention, however, has at most only about a 60% ERH, and is preferably not greater than about 55% ERH. Another measure of free water in foodstuffs can be provided by the amount of biological growth within the composition. In the present invention, the biological activity is less than about 100 ppm, preferably less than about 25 ppm, and most preferably less than 10 ppm.

It is a further aspect of the invention that at least some, and preferably most or

all, of the confectionery compositions according to the various embodiments set forth above be advantageously provided in the form of a shearform matrix, as that term is defined hereunder, as shearform matrix materials can exhibit significantly enhanced wettability because of a randomized structure resulting from flash-flow processing or high or low shear mixing, hereinafter described. Shearform matrix is particularly desirable because intimate admixture of all the ingredients is advantageously obtained. The matrix is such that when an encapsulation is further included, such as caffeine, the active ingredient is well dispersed throughout the entire confectionery as the encapsulation is well dispersed.

Shearform matrix refers to the product prepared by the method of flash-flow processing, a method which mixes and conditions ingredients for intimate contacting and enhanced hydration described, for example, in U.S. Patent No. 5,587,198 and its progeny. The term flash-flow has become recognized in the art as referring to a process which uses conditions of temperature and force to transform a solid feedstock having a certain morphological and/or chemical structure into a different morphological and/or chemical form without subjecting the solids to excessive heat or other requirements inherent in extrusion processing. The resultant structure has now been referred to as a shearform matrix. The terms flash-flow and shearform matrix are further described and set forth in commonly-owned U.S. Patent Nos. 5,236,734, 5,238,696, 5,518,730, 5,387,431, 5,429,836, 5,582,855 and 5,834,033.

Flash-flow processing can be advantageous in the present invention since it is useful for preparing ingredients to be easily and quickly mixed and hydrated. Another very important result of flash-flow processing is intimate mixing of the ingredients. Intimate mixing has traditionally been achieved by the use of water as a mixing medium. Flash-flow processing, however, intimately contacts ingredients and randomizes ingredient location and structure of the resulting shearform matrix. Randomizing the structure can be thought of as opening the physical and/or chemical structure for hydration. Thus, flash-flow processing not only ensures intimate mixing of ingredients without the use of water as a medium, but also conditions the ingredients for subsequent wetting with a minimum of water.

Flash-flow processing can be accomplished either by a flash-heat method or via

the somewhat less preferred flash-shear method, as described further herein. In the flash-heat process, the feedstock is heated sufficiently to create an internal flow condition, which permits internal movement of the feedstock at a subparticle level, and to exit openings provided in the perimeter of a spinning head. The centrifugal force created in the spinning head flings the flowing feedstock material outwardly from the head so that it reforms with a changed structure, i.e. a shearform matrix. The force necessary to separate and discharge flowable feedstock is provided by centrifugal force and the force of the ambient atmosphere impinging on feedstock exiting the spinning head.

One apparatus for implementing a flash-heat process is a cotton candy fabricating type machine. Other apparatus which provides similar forces and temperature gradient conditions substantially equivalent to flash-heat can also be used.

In particular, a spinning machine developed by Fuisz Technologies Ltd. of Chantilly, VA and patented under U.S. Patent No. 5,458,823 may be especially preferred for the flash-heat process. This patent describes a spinning machine which has a series of elongated heating elements arranged in between a base and a cover. The heating elements, base and cover together define a chamber into which a non-solubilized feedstock material is inserted which is capable of intraparticle flow upon application of heat and force. Means are provided for individually heating each of the elongated heating elements, and restriction means in the form of a cylindrical shell or annular plate which circumscribes the heating elements permits restrictive flow of the processed feedstock which is expelled from the chamber.

In the flash-shear process, a shearform matrix is produced by raising the temperature of the feedstock, which includes a non-solubilized carrier such as a saccharide material, until the carrier undergoes internal flow upon application of a fluid shear force. The feedstock is advanced and ejected while in internal flow condition, and subjected to disruptive fluid shear force to form multiple parts or masses which have a morphology different from that of the original feedstock.

The flash-shear process can be carried out in an apparatus which has means for increasing the temperature of a non-solubilized feedstock and means for simultaneously advancing it for ejection. A multiple heating zone twin screw extruder can be used for increasing the temperature of the non-solubilized feedstock. A second element of the apparatus is an ejector which reduces the feedstock to a condition for shearing. The ejector is in fluid communication with the means for increasing the temperature and is arranged at a point to receive the feedstock while it is in internal flow condition. The flash-shear process and apparatus are described in U.S. Patent No. 5,380,473, which is incorporated herein by reference. Of the flash-heat and flash-shear processes herein described, flash-heat appears to be much more readily adaptable to the process of the invention. However, those skilled in the art may find that flash-shear methodology can be adjusted to their particular needs.

Thus, one or more components of the composition of the invention may be advantageously processed using flash-flow procedures, e.g. flash-heat or flash shear. Particularly well adapted for flash-flow processing is the saccharide-based component of the soft and chewy nougat-like confectionery herein described. Maltodextrin, for example, may be utilized as the feedstock to process through the flash-flow apparatus. The saccharide-based component can also serve as a carrier material for piggybacking some of the other constituents which may also be flash-flow processed with the saccharide-based component, e.g. one or more of the emulsifiers, oils, fats, flavorings, and sweeteners etc., as well as one or more of the active materials. As a result of being flash-flow processed, the saccharide-based component and any optional ingredients are provided in the form of a shearform matrix, as set forth above.

Also highly suitable for flash-flow processing are one or more of the active ingredient encapsulations, as heretofore described.

One embodiment of the present invention may also include pre-flash-flow processing of certain ingredients. Pre-flash-flow processing is simply flash-flow processing of one or more ingredients before combining these with either the saccharide-based component or the hydrobinding component for additional flash-flow processing or additional admixing. Flash-flow processing results in increased surface area and increased solubility of the ingredients subjected thereto, and contributes to

actual binding of the ingredients to each other, and therefore, preliminary or pre-flash-flow processing may be particularly advantageous to the skilled artisan.

Another means for processing the components making up the compositions of the invention is via low and high shear mixing processes. In some instances, the added time and expense associated with flash-flow processing (or pre-flash-flow processing) may be significantly reduced or avoided. The same qualities associated with the final product (e.g. shear-form matrix attributes, intimate mixing, no cooking) can be attained through the use of the shear mixing methods as would be attained through the use of flash-flow processing.

As that term is used herein, high shear mixing refers to relatively intensive mixing action concentrated in a localized area. The high speed impact of mixing mechanisms such as blades or choppers results in shearing action. This in turn creates localized high shear force and a fluidizing effect at the point of contact, which causes particular scale diffusion and disagglomeration and faster mixing in a relatively small area of the entire mixing volume, i.e. the formation of a localized shearform matrix. High shear mixing may also result in increased temperature at the point of impact of the shearing apparatus with the mix, thereby further contributing to the effective mixing action.

High shear mixing should be contrasted with low shear mixing in which the main action of mixing is due to the relative motion of a much larger volume of mix being circulated by the spinning or churning action of a lower impact type mechanism, such as a paddle-blade typically found in a Sigma or Hobart mixer. Whenever high or low shear mixing is utilized to produce the functionalized confectionery mass of the present invention, the resultant product can be referred to as both uncooked (in the sense that excessive heat is not utilized) and unspun (in the sense that a flash-flow apparatus is not utilized). The product is also in the form of shearform matrix.

Thus, any number of the components comprising the composition of the invention may be mixed together through the use of high or low shear mixing, as well as flash-flow processing, as well as any combination thereof. For example, as heretofore noted, it may be particularly preferred to flash-flow process the saccharide-based component along with certain of the above-cited adjunct ingredients, including

any active material(s). (As also previously noted, it may also be desirable to pre-flash-flow process one or more of the actives before further flash-flow processing with the saccharide material). The materials making up the hydrobinding component such as the cited gums, gelatin and glycerine can then be combined and hydrated, for example, using high or low shear mixing. The final composition can then be formed by combining all the aforementioned components, again by utilizing either high or low shear mixing, preferably high shear mixing. Upon combining the hydrated hydrobinding component, the saccharide-based component, the other ingredients, and any actives, moisture is readily imbibed and disseminated throughout the non-hydrated components and/or ingredients. Again, unlike prior art methods and confectionery compositions, additional moisture is not required to form a hydrated mixture. Thus, excess water is not present in the resulting mass, and no cooking or heating is then required to drive off this excess moisture.

In still another embodiment of the invention, it may be desirable to process all materials using high shear mixing. For example, the saccharide-based component, optional ingredients, and any actives may be admixed using high shear. The ingredients constituting the hydrobinding component may also be processed using high shear. The final formulation can be achieved by then submitting all components to high shear mixing. Alternatively, it is also contemplated to process all components using low shear mixing.

An especially preferred high-shear mixer for use with the invention is known as a Littleford FKM 1200. This device provides high shear mixing by proximal shearing blades which are at right angles to one another. The shearing blades consist of plowers and choppers, both of which are utilized for high shear mixing action. While not wishing to be bound by any particular theory, it is believed that high shear action provides both mixing and heating at the localized points of blade contact with the mix ingredients, thereby resulting in excellent dispersibility without the undesired effects of lumping etc. Other high shear mixers (with one or more mixing blades), currently available or yet to be developed, are also contemplated by the method of the invention.

If desired, the high shear mixer can be further equipped with a jacket heater to provide the benefits of additional warming. A preferred temperature range is from

about 30 degrees C to about 60 degrees C, more desirably within the range of about 30 degrees to about 45 degrees C.

A preferred procedure for high shear mixing is as follows: The jacket heater on the high shear mixer is first activated and allowed to warm to a temperature of about 40 degrees C. Next, the saccharide-based component and other dry ingredients may be fed through the open hopper and allowed to mix using the plowers provided on the apparatus. For an 18 pound mixture, for example, the device is first run for about 2 minutes. Any added fat, along with emulsifiers, and the liquid-based hydrobinding component (which has been previously prepared using low shear mixing), together with any flavorings, sweeteners and coloring, are then fed into the mixer, and the choppers or high shear blades are activated to further complete the mixing. During this time, the jacket temperature may be increased to within the range of about 50-60 degrees C, preferably about 58-60 degrees to assist in the mixing, especially if fat is present in the mixture. The mixer is then run for about 5-10 minutes more, perhaps longer, to complete the mixing of the saccharide-based component and the hydrobinding component. Once mixing is complete, the entire matrix is then emptied into an appropriate container for slicing, sorting, packaging and shipping etc., e.g. is extruded and cut into dosage size pieces.

In certain instances, the use of low shear mixing apparatus can also provide the product of the invention. Of these, a Sigma mixer and/or Hobart industrial paddle mixer may be suitable. In one preferred embodiment, the dry ingredients (saccharide-based component and any additional materials, including active ingredients) are mixed in a Sigma mixer until a good consistency is obtained. Separately, the liquid ingredients (hydrobinding components) along with any active ingredients (encapsulations) are mixed and allowed to hydrate in a Hobart mixer, and then added to the Sigma mixer with the dry ingredients. The whole mixture is then run in the Sigma mixer for about 3 minutes. Variations of the foregoing process are certainly within the scope of the invention, depending upon the characteristics of the individual ingredients, and the attributes desired within the final product.

Finally, another method of formulating the product of the invention may comprise the utilization of both high- and low-shear mixing apparatus set forth above,

depending upon the needs of the skilled artisan.

EXAMPLES -

For a better understanding of the present invention, together with other and further objects, the following examples (with tables) are provided to illustrate the unique methods of making a chewy confectionery mass and an encapsulated product matrix. These examples should not be construed as limiting the scope of the invention.

Unless otherwise specified, percentages of components in the composition are given as percentage by weight (wt%). Also, unless otherwise indicated, all materials were obtained from commercial suppliers:

EXAMPLE 1 - In this example, a soft and chewy nougat was prepared having the ingredients set forth in TABLE 1 below. An encapsulation was prepared using low shear mixing apparatus and combined with the remaining ingredients under low shear as well (Sigma mixer). The yield was a sweet-tasting, chewy confectionery which delivered 60 mg. of caffeine in a single-size dose (about 5 - 6 grams). Neither the taste or grittiness of the caffeine was discernible.

TABLE 1

Component	Qty% in Final
Confectioner's Sugar 6X Powder	30 - 35
Maltodextrin	30 - 35
Cocoa Powder	8
Sorbitol	5
Xylitol	1
Flavor*	2
Aspartame	0.12
Acesulfame Potassium	0.10
Partially Hydrogenated Soybean Oil	4
Lecithin	1
Tap Water	6
Gelatin Type B 250 Bloom	1.8

Component	Qty% in Final
Glycerin 99%	3
Gum Arabic	0.4
Caffeine Encapsulation**	3.5

*included cream flavor, vanilla powder and natural and artificial chocolate flavor.

** included the following: caffeine powder (35%), fat (Stearine 17) (38%), emulsifier (Myvacet 707) (2.5%), cocoa powder and/or coffee/coffee flavor (11%), food-grade wax (10%) and artificial sweetener (aspartame) (3.5%).

Example 2 - In this example, a cocoa flavored caffeine encapsulation formulation was prepared according to the ingredients set forth in Table 1 below:

TABLE 2

Component	Qty %
<u>Active(s):</u>	
Caffeine	20 - 30
Other actives*	0.5 - 15
<u>Fats/Emulsifiers:</u>	
Edible Wax	0.1 - 5
Food Grade Oils	40 - 60
<u>Sweeteners/Flavors:</u>	
Cocoa Powder	1 - 10
Chocolate Flavor	1 - 10

The ingredients in TABLE 2 were mixed and extruded to yield 500 grams total of processed material, containing approximately 100 - 150 grams of caffeine. *Optional green tea extract and ginseng were provided in this formulation. The encapsulated caffeine matrix so prepared was mixed into a chocolate chewy nougat type confectionery base, as well as a chewy caramel/chocolate confectionery base. In both of the resulting confectioneries, there was no perception of either the taste or texture of caffeine.

Example 3 - In this example, an encapsulated caffeine matrix was prepared without any

flavorants or sweeteners according to the formulation set forth in Table 3 below:

TABLE 3

Component	Qty %
<u>Active(s):</u>	
Caffeine	30 - 40
<u>Fats/Emulsifiers:</u>	
Edible Wax	15 - 20
Food Grade Oils	40 - 50
Acetylated Mono- and diglycerides	5

The ingredients in TABLE 3 were mixed and extruded to yield 500 grams total of processed material, containing approximately 150 - 200 grams of caffeine. The encapsulated caffeine matrix so prepared was mixed into a chocolate chewy nougat type confectionery base, as well as a chewy caramel/chocolate confectionery base. In both of the resulting confectioneries, there was no perception of either the taste or texture of caffeine. An identical formulation to that set forth in Table 3 was also prepared, with the exception that the loading of mono- and diglycerides was only 2%. An independent panel of tasters reported that this formulation was bitter, with a noticeable taste of caffeine.

Example 4 - In this example, an encapsulated caffeine matrix was prepared using flavorant and sweetener according to the formulation set forth in Table 4 below:

TABLE 4

Component	Qty %
<u>Active(s):</u>	
Caffeine	30 - 40
<u>Fats/Emulsifiers:</u>	
Edible Wax	15 - 20
Food Grade Oils	40 - 50
Acetylated Mono- and diglycerides	5
<u>Flavor(s):</u>	
Natural Lemon	5

<u>Gums:</u>	
Gum Arabic	3
<u>Sweetener(s):</u>	
Aspartame	2

The ingredients in TABLE 4 were mixed and extruded to yield 500 grams total of processed material, containing approximately 150 - 200 grams of caffeine. The encapsulated caffeine matrix so prepared was mixed into lemon-flavored chewy nougat type confectionery base. In both of the resulting confectioneries, there was no perception of either the taste or texture of caffeine. An identical formulation to that set forth in Table 4 was prepared, with the exception that the loading of mono- and diglycerides was only 2%. An independent panel of tasters reported that this formulation was bitter, with somewhat pronounced caffeine organoleptic sensation.

Thus, while there have been described what are primarily believed to be the preferred embodiments, those skilled in the art will appreciate that other and further changes and modifications can be made without departing from the true spirit of the invention, and it is intended to include all such changes and modifications within the scope of the claims which are appended hereto.

WE CLAIM:

1. A composition in the form of an encapsulated matrix, said matrix comprising caffeine and at least one material selected from the group consisting of oleaginous substances, wherein said composition has substantially no organoleptic caffeine sensation.
2. The composition according to claim 1, wherein said matrix further comprises at least one member selected from the group consisting glycerol derivatives.
3. The composition according to claim 2, wherein said glycerol derivatives are selected from the group consisting of mono-, di-, and triglycerides and their fatty acids esters, and combinations thereof.
4. The composition according to claim 3, wherein said glycerol derivatives are mono- and diglycerides, and combinations thereof.
5. The composition according to claim 3, wherein said glycerol derivatives comprise at least about 3% of said composition.
6. The composition according to claim 5, wherein said glycerol derivatives comprise from about 3 to 15% of said composition.
7. The composition according to claim 6, wherein said glycerol derivatives comprise from about 3 to 8% of said composition.
8. The composition according to claim 3, said composition further comprising at least one member selected from the group consisting of flavorants and sweeteners.
9. The composition according to claim 8, wherein said flavorants are at least one member selected from the group consisting of cocoa, cocoa powder, chocolate and coffee.
10. The composition according to claim 9, wherein said glycerol derivatives comprise

less than about 3% of said composition.

11. The composition according to claim 8, wherein said flavorant is at least one member selected from the group consisting of natural and synthetically derived fruit essences, flavors and oils.

12. The composition according to claim 11, wherein said sweetener is at least one member selected from the group consisting of natural and artificial sweeteners.

13. The composition according to claim 12, wherein said glycerol derivatives comprise at least about 3% of said composition.

14. A composition in the form of an encapsulated matrix, said matrix comprising from about 10 to 50% caffeine and at least one material selected from the group consisting of oleaginous substances wherein said oleaginous substances include at least one member selected from the group consisting of glycerides in an amount of at least about 3%, wherein said composition has substantially no organoleptic caffeine sensation in a confectionery base selected from the group consisting of caramel and chocolate flavors and combinations thereof.

15. A composition in the form of an encapsulated matrix, said matrix comprising from about 20 to 40% caffeine, at least one material selected from the group consisting of oleaginous substances wherein said oleaginous substances include at least one member selected from the group consisting of glycerides in an amount of at least about 3% and at least one member selected from the group consisting of fruit essences, oils, and flavors in amount of from about 0.1 to 10%, wherein said composition has substantially no organoleptic caffeine sensation in a confectionery base selected from the group consisting of fruit flavors and combinations thereof.

16. The composition according to claim 15, wherein said flavorant is lemon and said confectionery base is at least one member selected from the group of citrus flavors.

17. The composition according to Claim 15, said composition further comprising at least one sweetener in an amount of at least about 1 %.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/18202

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A23G3/00 A61K9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☒ Further documents are listed in the continuation of box C

☒ Patent family members are listed in annex

* Special categories of cited documents:

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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information on patent family members

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